

SS IEC 60601-1:2018+A1:2020
IEC 60601-1:2005+AMD2:2020, IDT
(ICS 11.040.01)

SINGAPORE STANDARD

Medical electrical equipment

– Part 1: General requirements for basic safety
and essential performance

Incorporating Amendment No. 1

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– Part 1: General requirements for basic safety and essential performance

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BHSC consists of the following members:

	Name	Representation
Chairman	: Dr Yong Chern Chet	<i>Individual Capacity</i>
Deputy Chairmen	: Mr Vincent Cheung	<i>Individual Capacity</i>
	Ms Selina Seah	<i>Changi General Hospital</i>
	Ms Wong Woei Jiuang	<i>Health Sciences Authority</i>
Advisor	: Ms Jacqueline Monteiro	<i>Individual Capacity</i>
Secretary	: Ms Iris Peng	<i>Singapore Manufacturing Federation – Standards Development Organisation</i>
Members	: Mr Alec Chow Boon Kuan	<i>Medtronic International Ltd</i>
	Mr Chung Kwong Yuew	<i>Temasek Polytechnic (BioMedical Engineering Faculty)</i>
	Ms Heidi Goh	<i>Singapore Manufacturing Federation (Medical Technology Industry Group)</i>
	Prof James Goh	<i>Biomedical Engineering Society (Singapore)</i>
	Dr Lai Choon Sheen	<i>Eu Yan Sang International Ltd</i>
	Dr Christopher Lam	<i>Health Sciences Authority</i>
	Assoc Prof Leo Hwa Liang	<i>National University of Singapore</i>
	Dr Lin Jianhua	<i>TÜV SÜD PSB Pte Ltd</i>
	Dr Leonard Loh	<i>Nanyang Polytechnic</i>
	Assoc Prof Eddie Ng Yin Kwee	<i>Nanyang Technological University</i>
	Dr Ong Siew Hwa	<i>Acumen Research Laboratories Pte Ltd</i>
	Dr Padmanabhan Saravanan	<i>Temasek Polytechnic (Centre of Innovation for Complementary Health Products)</i>
	Mr Peh Ruey Feng	<i>Advent Access Pte Ltd</i>
	Ms Celine Tan	<i>Enterprise Singapore</i>
	Prof Tan Puay Hoon	<i>Singapore Health Services Pte Ltd</i>
	Ms Wang Dan	<i>Biosensors International Group</i>
	Dr Sidney Yee	<i>Diagnostics Development (DxD) Hub</i>
	Dr Zhou Zhihong	<i>Singapore Bioimaging Consortium</i>

BHSC set up the Technical Committee on Medical Devices to oversee the preparation of this standard. The Technical Committee consists of the following members:

	Name	Representation
Chairman	: Prof James Goh	<i>Individual Capacity</i>
Secretary	: Ms Iris Peng	<i>Singapore Manufacturing Federation – Standards Development Organisation</i>
Members	: Ms Chua Chui Khim	<i>Becton Dickinson Medical (S) Pte Ltd</i>
	Dr Christopher Lam	<i>Health Sciences Authority</i>
	Assoc Prof Leo Hwa Liang	<i>Biomedical Engineering Society (Singapore)</i>
	Dr Lim Jing	<i>Osteopore International Pte Ltd</i>
	Ms Iris Tan	<i>Advent Access Pte Ltd</i>

The Technical Committee set up the National Mirror Working Group on IEC SC62D MT20 to prepare this standard. The Working Group consists of the following experts who contribute in their *individual capacity*:

	Name
Convenor	: Dr Christian Gert Bluechel
Secretary	: Mr Kevin Tan
Members	: Mr Peter Haywood
	Dr Ho Teck Tuak
	Mr Watson Ong
	Mr Peh Ruey Feng
	Prof Tong Yen Wah

The organisations in which the experts of the Working Group are involved are:

Advent Access Pte Ltd

AWAK Technologies Pte Ltd

Kidney Dialysis Foundation

National University of Singapore

Temasek Polytechnic

The Institution of Engineers, Singapore

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National Foreword

This Singapore Standard was prepared by the Working Group on IEC SC62D MT20 set up by the Technical Committee on Medical Devices under the purview of BHSC.

This standard is identical with IEC 60601-1:2005, "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance", including the amendments to this edition, published by the International Electrotechnical Commission.

NOTE 1 – Where appropriate, the words "International Standard" are read as "Singapore Standard".

NOTE 2 – Reference to International Standards are replaced by applicable Singapore Standards.

NOTE 3 – Where numerical values are expressed as decimals, the comma is read as a full point.

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3. *Compliance with a SS or TR does not exempt users from any legal obligations.*

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-1 edition 3.2 contains the third edition (2005-12) [documents 62A/505A/FDIS and 62A/512/RVD], its amendment 1 (2012-07) [documents 62A/805/FDIS and 62A/820/RVD] and its amendment 2 (2020-08) [documents 62A/1389/FDIS and 62A/1404/RVD].

This Consolidated version includes the contents of the corrigenda 1 (2006-12) and 2 (2007-12), the contents of the corrigendum to Amendment 1 (2014-07), as well as the interpretation sheets 1 (2008-04), 2 (2009-01) and 3 (2013-05).

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International Standard IEC 60601-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999). This

edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Annex A.3.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard the following print types are used:

- Requirements and definitions: in roman type.
- *Test specifications: in italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex G of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for

conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The “colour inside” logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

INTRODUCTION

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

- the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);
- the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;
- the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and
- the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, "The ability of an electric kettle to boil water is not critical to its safe use!"

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12]¹⁾ in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles:

- the first change is that the concept of “SAFETY” has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from “Medical electrical equipment, Part 1: General requirements for safety” in the second edition, to “Medical electrical equipment, Part 1: General requirements for basic safety and essential performance”;
- the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2).

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

Amendment 1 to this standard is intended to address:

- issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;
- the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and
- the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005.

Throughout this document, there are many references to, and requirements incorporated from IEC 60950-1. Some of these requirements are derived from IEC 60950-1. For example, the requirements for spaces filled by insulating compound in 8.9.3. In other cases, the requirements are incorporated by a normative reference to IEC 60950-1:2005. For example, the requirements for solid insulation forming a MEANS OF OPERATOR PROTECTION in 8.5.1.3. The requirements incorporated by reference are primarily found in Clause 8 of this document, including many of the tables used to determine the requirements for MEANS OF PROTECTION, primarily MEANS OF OPERATOR PROTECTION and INSULATION CO-ORDINATION. The requirements incorporated by reference are addressed in Amendment 2. The derived requirements will be addressed during the development of the fourth edition of this document.

1) Figures in square brackets refer to the Bibliography.

INTRODUCTION TO AMENDMENT 1

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties.

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

- those listed in 62A/593/DC and 62A/602/INF;
- the way in which risk management has been introduced into IEC 60601-1:2005; and
- the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issue Sheets. This amendment is intended to address those issues.

INTRODUCTION TO AMENDMENT 2

The third edition of IEC 60601-1 was published in 2005 and amended in 2012. Since the publication of IEC 60601-1:2005/AMD1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees and questions submitted to IEC/SC 62A/Working Group (WG) 14. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in Amendment 2 and should not wait until the fourth edition of IEC 60601-1, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 109 items were presented to the National Committees present. A total of 78 items received the required 2/3 majority of the National Committees present and voting and were included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1.

The "short list" of issues was documented in the design specification for Amendment 2. The responsible expert groups were directed to consider each issue assigned to it in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to the 2005 edition of IEC 60601-1, the style in force at the time of publication of IEC 60601-1 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1.

NOTE 1 See also 4.2.

The IEC 60601 series does not apply to:

- in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];
- implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or
- medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.

1.2 Object

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

1.3 * Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:

- a subgroup of ME EQUIPMENT (e.g. radiological equipment);
- a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

Applicable collateral standards shall apply together with this standard.

NOTE 1 When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.

NOTE 2 When declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This allows the reader of the declaration to understand which collateral standards were part of the evaluation.

NOTE 3 Collateral standards in the IEC 60601 family are numbered IEC 60601-1-xx. The IEC maintains a catalogue of valid International Standards. Users of this standard should consult this catalogue at "<http://webstore.iec.ch>" to determine which collateral standards have been published.

1.4 * Particular standards

In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in this standard and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration.

NOTE Particular standards in the IEC 60601 family that are developed by IEC committees are numbered IEC 60601-2-xx. In addition, particular standards developed by joint projects between ISO and IEC can be numbered either IEC 80601-2-xx or ISO 80601-2-xx depending on which committee administered the project. IEC and ISO maintain catalogues of valid International Standards. Users of this standard should consult these catalogues at "<http://webstore.iec.ch>" and "<http://www.iso.org/iso/store.htm>" to determine which particular standards have been published.

A requirement of a particular standard takes priority over this standard and applicable collateral standards.

2 * Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, shall apply together with this standard when applicable. They shall be considered as being included among the normative references below. See 1.3.

NOTE Informative references are listed in the Bibliography on page 396.

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements* ²⁾
Amendment 1:2005
Amendment 2:2010

IEC 60068-2-2:2007, *Environmental testing – Part 2-2: Tests – Test B: Dry heat*

IEC 60079-0, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures “p”*

IEC 60079-5, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling “q”*

IEC 60079-6, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion “o”*

IEC 60083, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

IEC 60085, *Electrical insulation – Thermal classification*

IEC 60086-4, *Primary batteries – Part 4: Safety of lithium batteries*

IEC 60112, *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

²⁾ There exists a consolidated edition 7.2 including IEC 60065:2001 and its Amendment 1 (2005) and Amendment 2 (2010).

IEC 60127-1, *Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

IEC 60227-1:2007, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements*

IEC 60245-1:2003, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*³
Amendment 1:2007

IEC 60252-1, *AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation*

IEC 60320-1, *Appliance couplers for household and similar general purposes – Part 1: General requirements*

IEC 60335-1:2010, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60364-4-41, *Electrical installations of buildings – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60384-14:2005, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

IEC 60417, *Graphical symbols for use on equipment*. Available from: <<http://www.graphical-symbols.info/equipment>>

IEC 60445, *Basic and safety principles for man-machine interface, marking and identification – Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system*

IEC 60447, *Basic and safety principles for man-machine interface, marking and identification – Actuating principles*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)* ⁴⁾
Amendment 1 (1999)

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*
Amendment 1:2020

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance. Collateral standard: Radiation protection in diagnostic X-ray equipment*
Amendment 1:2013

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic and essential performance – Collateral standard: Usability*
Amendment 1:2013
Amendment 2:2020

³⁾ There exists a consolidated edition 4.1 including IEC 60245-1:2003 and its Amendment 1 (2007).

⁴⁾ There exists a consolidated version 2.1, including IEC 60529:1989 and its Amendment 1 (1999).

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012
Amendment 2:2020

IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*
IEC 60695-11-10, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

IEC 60730-1:2010, *Automatic electrical controls for household and similar use – Part 1: General requirements*

IEC 60747-5-5:2007, *Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers*

IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

IEC 60851-3:2009, *Winding wires – Test methods – Part 3: Mechanical properties*

IEC 60851-5:2008, *Winding wires – Test methods – Part 5: Electrical properties*

IEC 60851-6:1996, *Winding wires – Test methods – Part 6: Thermal properties*
Amendment 1 (1997)

IEC 60884-1, *Plugs and socket-outlets for household and similar purposes - Part 1: General requirements*

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
Amendment 1:2009
Amendment 2:2013

IEC 61058-1:2000, *Switches for appliances – Part 1: General requirements* ⁵⁾
Amendment 1:2001
Amendment 2:2007

IEC 61558-2-1, *Safety transformers, power supply units and similar – Part 2: Particular requirements for separating transformers for general use*

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 61965, *Mechanical safety of cathode ray tubes*

IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*

⁵⁾ There exists a consolidated edition 3.2, including IEC 61058-1:2000 and its Amendment 1 (2001) and Amendment 2 (2007)

IEC 62304:2006, *Medical device software – Software life cycle processes*
Amendment 1:2015

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

ISO 780, *Packaging – Pictorial marking for handling of goods*

ISO 1853, *Conducting and dissipative rubbers, vulcanized or thermoplastic – Measurement of resistivity*

ISO 2878, *Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance*

ISO 2882 ⁶⁾, *Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits*

ISO 3746, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 3864-1:2002, *Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs in workplaces and public areas*

ISO 5349-1, *Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements*

ISO 7000, *Graphical symbols for use on equipment*

ISO 7010:2019, *Graphical symbols – Safety colours and safety signs – Registered safety signs*

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 13857:2008, *Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs*

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

ISO 15223-1:2016, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 23529, *Rubber – General procedures for preparing and conditioning test pieces for physical test methods*

⁶⁾ ISO 2882 was withdrawn on 1 February 2005 and no replacement standard has been identified.

ISO 80000-1:2009, *Quantities and units – Part 1: General*